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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,793	06/09/2006	Guy Vancanneyt	58764.000055	3642

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HUNTON & WILLIAMS LLP
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WASHINGTON, DC 20006-1109

EXAMINER

ZHENG, LI

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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07/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,793	Applicant(s) VANCANNEYT ET AL.	
	Examiner LI ZHENG	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,15-17,24,27 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,15-17,24,27 and 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/15/2009; 4/29/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-2, 15-17, 24, 27 and 31-37 are pending and examined on the merits.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2009 has been entered.

Applicant's submission of new claims 31-27 filed on April 21, 2009 is acknowledged.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejections and objections that are not recited in this Office Action are considered as being withdrawn.

Claim Rejections - 35 USC § 103

5. Claims 1-2, 15-17, 24 and 27 remain rejected and claims 31-37 are under 35 U.S.C. 103(a) as being unpatentable over Yanofsky et al. (2006, U.S. Patent No. 7,135,621; '621 patent hereafter) in view Smith et al. (2000, *Nature*, 407:319-320), for the reasons of record stated in the Office action mailed July 23, 2009. Applicants traverse in the paper filed April 21, 2009. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the Office fails to articulate why one of skill in the art would add a construct that enhances gene silencing to achieve a method that weakens gene silencing (response, page 5, the last two paragraphs from the bottom of the page).

The Office contends that the milder silencing of the instant invention is primarily achieved by using heterologous IND1 gene from Arabidopsis because of the relatively low homology between the dsRNA and endogenous gene. Although it has shown in Arabidopsis that hairpin structure could increase the efficiency of gene silencing, antisense and hairpin constructs are considered an obvious design choice for gene silencing because the overall silencing strength is not simply dependent on antisense and hairpin constructs, but also on the homology between the fragment of SEQ ID NO: 1 used for making the construct and the corresponding homologous region in the endogenous IND gene in Brassica plant. Without knowing exact the homology between the fragment of SEQ ID NO: 1 used for making the construct and the corresponding homologous region in the endogenous IND gene in Brassica plant, it would have been

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obvious to test different promoters with various strength in Brassica and different design of the silencing construct including antisense and hairpin vectors. For example, a construct comprising an antisense of IND driven by a stronger promoter may have similar silencing effect as a construct comprising a hairpin structure driven by a weaker promoter.

Applicants further argue that the specification demonstrates unexpected results (response, page 6, 2nd paragraph). Applicants particularly point out that Example 2B supports the statement that the invention is based on the unexpected observation that moderate dsRNA gene silencing of genes involved in the development of the dehiscence zone and valve margins of pod in Brassicaceae plants allows the isolation of transgenic lines with increased pod shatter resistance and reduced seed shattering, the pods of which however may still be opened along the dehiscence zone by limited physical forces (response, page 6, 2nd paragraph).

The Office contends that the result is not unexpected given the antisense construct of Yanofsky would result in moderate dsRNA gene silencing of IND1 homologous genes in Brassicaceae plants and would allow the isolation of transgenic lines with increased pod shatter resistance and reduced seed shattering, the pods of which however may still be opened along the dehiscence zone by limited physical forces. Applicants are invited to provide evidence showing that transgenic Brassica plant comprising antisense construct of Yanofsky would not exhibit those properties as claimed.

Applicants further argue that Dr. Botterman's Declaration demonstrate unexpected results (response, page 6, 2nd paragraph). Particularly, Dr. Botterman's Declaration argues that Yanofsky's disclosure of two IND1 orthologs from *Brassica napus* is not prior art to the instant application (response, page 7, 2nd paragraph) and that the claimed invention concerns the weakening of gene silencing of the IND1 gene, whereas Smith concern enhancing gene silencing in general (response, the paragraph bridging pages 7-8)

The Office contends that whether the Yanofsky's disclosure of two IND1 orthologs from *Brassica napus* is a prior art or not is irrelevant to instant rejection since the instant claims are drawn to a method using a fragment of SEQ ID NO: 1 which is the IND1 gene from *Arabidopsis*. Regarding the argument that the claimed invention concerns the weakening of gene silencing of the IND1 gene whereas Smith concern enhancing gene silencing in general, the Office found the argument not persuasive for the reason as discussed above.

Applicants argue that at time of the invention a person with ordinary skill in the art would not have made any prediction of the degree of sequence identity between the *Arabidopsis* IND1 gene and the orthologs from *Brassica napus* plant (response, page 8, 2nd paragraph) and that a person with ordinary skill in the art would have known that silencing of the IND gene in *Arabidopsis thaliana* using dsRNA silencing resulted in almost complete potshatter resistance (response, page 8, 3rd paragraph).

The Office contends that as discussed earlier, knowing the degree of sequence identity between the *Arabidopsis* IND1 gene and the orthologs from *Brassica napus*

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plant is irrelevant to instant rejection given the prior teaching a method of suppressing expression of IND1 homologous gene in Brassicaceae plants by using antisense of IND1 gene from Arabidopsis. The patent is presumed to be valid and thus enabled.

Applicants further argue that Dr. Botterman's Declaration indicates that a person with ordinary skill in the art would not have been in a position to predict that the use of dsRNA based on parts of nucleotide sequence of IND1 from Arabidopsis would result in Brassica plants with an intermediate degree of gene silencing as claimed (response, the paragraph bridging pages 8-9).

The Office disagrees. Because the gene silencing significantly relies on sequence homology, the heterologous sequences of IND1 gene fragment is not expected to completely silence the IND1 homologous gene in Brassica plants.

6. Claims 1-2, 15-17, 24 and 27 remain rejected and claims 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liljegren et al. (2006, U.S. Patent No. 6,998,517) in view Smith et al. (2000, *Nature*, 407:319-320), for the reasons of record stated in the Office action mailed July 23, 2009. Applicants' traverse in the paper filed April 21, 2009. Applicants' arguments have been fully considered but were not found persuasive.

Applicants present similar arguments as discussed above. Therefore, for the same reason, the rejection is maintained. The Office invites Applicants to submit a 1.132 declaration disclosing unexpected results of the instantly claimed invention.

Double Patenting

7. Claims 1-2, 15-17, 24 and 27 remain rejected and claims 31-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-39 of U.S. Patent No. 6,998,517 in view Smith et al. (2000, *Nature*, 407:319-320), for the reasons of record stated in the Office action mailed July 23, 2009. Applicants traverse in the paper filed April 21, 2009. Applicants' arguments have been fully considered but were not found persuasive.

Applicants present similar arguments as discussed in the rejection under U.S.C 103 (a). Therefore, for the same reason, the rejection is maintained. The Office contends that a showing of unexpected results using the claimed invention will obviate the rejection.

8. Claims 1-2, 15-17, 24 and 27 remain rejected and claims 31-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-28 of U.S. Patent No. 7,135,621 in view Smith et al. (2000, *Nature*, 407:319-320), for the reasons of record stated in the Office action mailed July 23, 2009. Applicants traverse in the paper filed April 21, 2009. Applicants' arguments have been fully considered but were not found persuasive.

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Applicants present similar arguments as discussed in the rejection under U.S.C 103 (a). Therefore, for the same reason, the rejection is maintained. The Office contends that a showing of unexpected results using the claimed invention will obviate the rejection.

Summary

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David H Kruse/
Primary Examiner, Art Unit 1638